

K071709

510(k) Summary

Page 1 of 3

ArthroCare Corporation
ArthroCare® System 12000

AUG - 7 2007

General Information

Submitter Name/Address: ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, CA 94085-3523

Establishment Registration Number: 2951580

Contact Person: Valerie Defiesta-Ng
Director, Regulatory Affairs

Date Prepared: June 20, 2007

Device Description

Trade Name: ArthroCare® System 12000

Generic/Common Name: Electrosurgical Device and Accessories

Classification Name: Electrosurgical Cutting and Coagulation
Device and Accessories (Class II, 21 CFR
878.4400, Product Code GEI)

Predicate Devices

ArthroCare® System K032504

Product Description

The ArthroCare® System 12000 is a bipolar, high frequency, electrosurgical generator called the Controller that is intended to be used with a family of disposable, bipolar, single use Wands.

K071709

Page 2 of 3

Intended Uses

The ArthroCare System 12000 is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures:

Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
<i>Ablation and Debridement</i>	
• ACL/PCL	Knee
• Acromioplasty	Shoulder
• Articular Cartilage	All Joints
• Bursectomy	All Joints
• Chondroplasty	All Joints
• Fascia	All Joints
• Ligament	All Joints
• Notchplasty	Knee
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Subacromial Decompression	Shoulder
• Synovectomy	All Joints
• Tendon	All Joints
<i>Excision and Resection</i>	
• Acetabular Labrum	Hip
• Articular Labrum	All Joints
• Capsule	All Joints
• Capsular Release	Knee
• Cartilage Flaps	Knee
• Cysts	All Joints
• Discoid Meniscus	Knee
• Frozen Shoulder Release	Shoulder
• Glenoidale Labrum	Shoulder
• Lateral Release	Knee
• Ligament	All Joints
• Loose Bodies	All Joints
• Meniscal Cystectomy	Knee
• Meniscectomy	Knee

Continued

Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
• Plica Removal	All Joints
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Synovial Membrane	All Joints
• Tendon	All Joints
• Triangular Fibrocartilage (TFCC)	Wrist
• Villusctomy	Knee
Coagulation	
• ACL/PCL	Knee
• Articular Cartilage	All Joints
• Carpal Ligaments	Wrist
• Glenohumeral Capsule	Shoulder
• Ligament	All Joints
• Medial Retinaculum	Knee
• Rotator Cuff	Shoulder
• Tendon	All Joints
• Wrist Tendons	Wrist

Substantial Equivalence

In establishing substantial equivalence to the predicate device, ArthroCare compared the indications for use, dimensional specifications, and performance specifications of the subject device and the predicate device. Additionally, performance testing has been completed to demonstrate the substantial equivalence of the ArthroCare System 12000 to the predicate device. The performance testing and device comparison demonstrated that the subject device is substantially equivalent to the predicate device, and is safe and effective for its intended use.

Summary of Safety and Effectiveness

The ArthroCare System 12000, as described in this premarket notification 510(k), is substantially equivalent to the predicate device. The differences in performance specifications, and labeling are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2007

ArthroCare Corporation
% Ms. Valerie Defiesta-Ng
Director, Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, California 94085-3523

Re: K071709

Trade/Device Name: ArthroCare System 12000
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 20, 2007
Received: June 22, 2007

Dear Ms. Defiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Valerie Defiesta-Ng

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name ArthroCare System 12000


510(k) Number: K 071709

Page 1 of 2

Indications for Use:

The ArthroCare System 12000 is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures:

Arthroscopic and Orthopedic Procedures		Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
<i>Ablation and Debridement</i>		
• ACL/PCL		Knee
• Acromioplasty		Shoulder
• Articular Cartilage		All Joints
• Bursectomy		All Joints
• Chondroplasty		All Joints
• Fascia		All Joints
• Ligament		All Joints
• Notchplasty		Knee
• Scar Tissue		All Joints
• Soft Tissue		All Joints
• Subacromial Decompression		Shoulder
• Synovectomy		All Joints
• Tendon		All Joints
<i>Excision and Resection</i>		
• Acetabular Labrum		Hip
• Articular Labrum		All Joints
• Capsule		All Joints
• Capsular Release		Knee
• Cartilage Flaps		Knee
• Cysts		All Joints
• Discoid Meniscus		Knee
• Frozen Shoulder Release		Shoulder
• Glenoidale Labrum		Shoulder
• Lateral Release		Knee
• Ligament		All Joints
• Loose Bodies		All Joints
• Meniscal Cystectomy		Knee
• Meniscectomy		Knee


 (Division Sign-Off)
 Division of General, Restorative,
 and Neurological Devices

510(k) Number K071709

K071709

Page 2 of 2

Continued

Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
• Plica Removal	All Joints
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Synovial Membrane	All Joints
• Tendon	All Joints
• Triangular Fibrocartilage (TFCC)	Wrist
• Villusctomy	Knee
Coagulation	
• ACL/PCL	Knee
• Articular Cartilage	All Joints
• Carpal Ligaments	Wrist
• Glenohumeral Capsule	Shoulder
• Ligament	All Joints
• Medial Retinaculum	Knee
• Rotator Cuff	Shoulder
• Tendon	All Joints
• Wrist Tendons	Wrist

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 Prescription Use X
 (Per 21 CFR 801.109)

OR

Over-the-Counter Use


(Division Sign-Off)

 Division of General, Restorative,
 and Neurological Devices

 510(k) Number K071709